IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. HOSPIRA, INC. and PFIZER INC., Defendants.	)	C.A. No. 18-1064-CFC-CJB

AMGEN'S MOTION TO STRIKE HOSPIRA'S NEWLY-ASSERTED PRIOR-COMMERCIAL-USE DEFENSE UNDER 35 U.S.C. § 273

Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Amgen") respectfully move to strike a newly-asserted defense under 35 U.S.C. § 273 first disclosed by Defendants Hospira Inc. and Pfizer Inc. (collectively, "Hospira") less than two weeks ago. Section 273 provides a personal and fact-specific defense to infringement based on prior-commercial use. Hospira did not plead a § 273 defense in its Answer, nor raise this specific defense in its contentions or discovery responses. Rather, it is undisputed that Hospira first disclosed a § 273 defense to infringement in its pretrial exchanges on July 9, 2021,[1]

[1] Hospira states that its assertion of a § 273 defense is contingent upon the Court's grant of Amgen's pending motion for partial summary judgment of no invalidity under the prior knowledge and use provisions of 35 U.S.C. § 102(a) and § 102(b).

less than ten weeks before trial in this case is set to begin on September 20, 2021. (3/16/21 Oral Order.)

Hospira's belated disclosure is highly prejudicial to Amgen. Amgen has not had the opportunity to take discovery or prepare for trial on this defense, including facts and issues that do not overlap with any other defense in this case. Further, the jury trial in this case was delayed once before because of Hospira's decision to first disclose its on-sale bar and prior-knowledge-and-use defenses following the close of fact discovery. Amgen should not be prejudiced by another postponement of the trial because of Hospira's untimely disclosure of an unpled and undisclosed § 273 defense. Enough is enough. Amgen respectfully requests that Hospira's new § 273 defense be stricken.

A. Hospira's Eve-of-Trial Disclosure Is Untimely

Hospira did not plead in its Answer a specific defense to infringement based on prior-commercial use under § 273. (D.I. 51). Hospira also failed to raise § 273

(D.I. 207, D.I. 208.) But rather than asking for permission to add a new defense, Hospira simply inserted the § 273 defense into its pretrial disclosures. *See* Wu Decl. Wu Decl. Ex. A (Excerpt of Hospira Proposed Pretrial Order); Wu Decl. Ex. B (Hospira Proposed Verdict Form); Wu Decl. Ex. C (Excerpt of Hospira Proposed Jury Instructions); Wu Decl. Ex. D (Excerpt of Hospira Statement of Issues of Fact); Wu Decl. Ex. E (Excerpt of Hospira Statement of Issues of Law).

as a defense in its contentions and discovery responses, and otherwise failed to disclose the specific defense during fact and expert discovery. Indeed, Hospira failed to disclose the defense during the original fact discovery period that closed August 2019 (D.I. 26); the original expert discovery period that closed January 2020 (D.I. 26); the one-year supplemental fact discovery period that closed December 2020 (D.I. 129) which was necessitated by Hospira's disclosure in October 2019 of on-sale bar and prior-knowledge-and-use defenses after the close of fact discovery; and the supplemental expert discovery period that closed in January 2021 (D.I. 129). For example, Hospira did not disclose a § 273 defense in response to Amgen's interrogatory seeking "all factual and legal bases" for Hospira's contentions that it does not infringe the asserted claims—a response that Hospira supplemented as recently as December 22, 2020.

It was only on July 9, 2021 that Hospira added a defense under § 273 as part of its response to Amgen's pretrial disclosures. *See* Wu Decl. Ex. A; Wu Decl. Ex. B; Wu Decl. Ex. C; Wu Decl. Ex. D; Wu Decl. Ex. E. The fact that a § 273 defense was not specifically disclosed to Amgen before then is undisputed: during the parties' meet-and-confer process, Hospira's counsel could not identify any instances where a § 273 defense was specifically disclosed prior to July 9, 2021. Wu Decl. Ex. F (7/20/21 Email from P. Sandel to A. Hanstead). Rather, Hospira's

counsel asserted that no specific disclosure was required other than a general denial of infringement. *Id.*

Hospira's attempt to present to the jury—at a trial beginning in less than ten weeks—an unpled, undisclosed, and untimely defense is contrary to the Federal Rules and the Court's orders and, as discussed in the next section, is highly prejudicial to Amgen. It is well established that "Federal Rule of Civil Procedure 16 grants the Court broad discretion to issue sanctions if a party 'fails to obey a scheduling or other pretrial order.'" *Parallel Networks Licensing, LLC v. Microsoft Corp.*, No. CV 13-2073(KAJ), 2017 WL 11557656, at *1 (D. Del. Apr. 10, 2017) (citing Fed. R. Civ. P. 16(f)(1)(C) ("On motion or on its own, the court may issue any just orders . . . if a party or its attorney . . . fails to obey a scheduling order or other pretrial order.")). "In patent cases, courts have used that authority to strike untimely contentions." *Id.* (citing *O2 Micro Intern. Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1363 (Fed. Cir. 2006) ("The court may impose any 'just' sanction for the failure to obey a scheduling order, including 'refusing to allow the disobedient party to support or oppose designated claims or defenses, or prohibiting that party from introducing designated matters in evidence.")). Where, as here, the newly described theory is not anywhere in the record prior to pretrial exchanges, "it is untimely and should be excluded"; the attempt to introduce and

describe a new non-infringement theory now, with less than ten weeks to go before trial, "is a dramatic departure from the scheduling order" and "would place a heavy and unfair burden on [Amgen], which did not address the theory during discovery and would have to prepare to meet it at the imminent trial." *Id.* at *4.

Hospira asserts that its new defense is contingent upon the Court granting Amgen's motion for partial summary judgment of no invalidity under the prior knowledge and use provisions of 35 U.S.C. § 102(a) and § 102(b) (D.I. 207, D.I. 208). Ex. F. Hospira's concern that this prior-knowledge-and-use theory of invalidity fails as a matter of law does not justify Hospira's belated disclosure of yet another new defense on the eve of trial.

Hospira's claim that its new § 273 defense is based on the same facts as its prior-knowledge-and-use defense also does not excuse Hospira's untimely disclosure. Hospira first interjected its prior-knowledge-and-use theory of invalidity into the case (along with its on-sale bar theory of invalidity) in October 2019, after the original close of fact discovery. *See* Wu Decl. Ex. G at 34-44 (Excerpt of 12/6/19 Hr'g Tr.). Following that belated disclosure, the Court reopened discovery solely on those defenses (resulting in a delay of one year of the trial date) even though Hospira's conduct "was not certainly in the spirit of the manner in which cases should be conducted" and "Amgen has been prejudiced by

Hospira's conduct." Wu Decl. Ex. G at 44, 46.[2] However, at no point during or after that supplemental discovery period did Hospira assert, disclose, or seek permission to add an infringement defense under § 273.[3]

After the supplemental discovery period ended in January 2021, Amgen moved for partial summary judgment of no invalidity of the '997 Patent under the prior knowledge and use provisions of 35 U.S.C. § 102(a) and § 102(b). (D.I. 207, D.I. 208.) As Amgen's motion explained, the law requires Hospira to show that the claimed invention was accessible to the public in order to prevail on its prior-knowledge-and-use theories of invalidity under 35 U.S.C. §§ 102(a) and (b). (D.I. 208 at 3-4, 13-16.) But, even accepting all of Hospira's allegations as true, the secret use of the claimed invention by third-party PLIVA cannot establish the

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[2] The Court also provided guidance that "If Pfizer proceeds with the defense and loses, I am absolutely going to entertain a motion for costs, sanctions, fees, whatever, because Pfizer has made a lot of mistakes" and if Pfizer's allegations when accepted as true "still [aren't] going to be sufficient to prove an on-sale bar," then "there will be consequences, and they will be extreme for Pfizer if they lose this defense." Wu Decl. Ex. G at 53-54.

[3] Hospira should not have disclosed any new theories of non-infringement during the supplemental discovery period, as that period was limited to discovery on Hospira's "on sale bar and public use defenses," D.I. 129, but Hospira never even attempted to add the new defense to the case until slipping it into Hospira's July 9, 2021 pretrial disclosures.

public accessibility needed for Hospira's prior-knowledge-and-use defense to succeed, and thus Hospira's invalidity claim fails as a matter of law. (*Id.*)

In an apparent recognition of the weakness of its prior-knowledge-and-use defense, Hospira now attempts to interject an entirely new prior-commercial-use defense to infringement under § 273. Based on Hospira's limited disclosure of this newly-asserted § 273 defense, Hospira is apparently arguing that third-party PLIVA's secret (*i.e.*, non-public) use is premarketing regulatory review that constitutes commercial use under § 273(c)(1). According to Hospira's counsel, its defense under § 273 "would be based on the same facts and events on which Amgen took discovery for almost a year, and which were the basis for Amgen's Motion for Partial Summary Judgment of No Invalidity Under the Prior Knowledge and Use Provisions of 35 U.S.C. Section 102(a) and Section 102(b) (D.I. 207)." Wu Decl. Ex. F (7/15/21 E-mail from A. Hanstead to P. Sandel). That Hospira is attempting to rely on the "same facts" to allege a § 273 defense simply confirms that Hospira has no excuse for its untimely disclosure of this defense.

B. Hospira's Belated Disclosure Prejudices Amgen

Amgen is highly prejudiced by the disclosure of a new defense on the eve of trial when Hospira could have asserted it earlier and in accordance with the Court's

orders. Not only does the belated disclosure prejudice Amgen's ability to prepare for trial, but Amgen has not had the opportunity to take discovery on this issue.

1. That Hospira Repackages Facts From Its Invalidity Theories Does Not Mean Amgen Has Had An Opportunity to Take Discovery on the Newly-Asserted § 273 Defense, Which is a Personal Defense

Contrary to Hospira's assertion, the discovery taken on the on-sale bar and prior-knowledge-and-use invalidity defenses is not the same discovery that Amgen would have sought on Hospira's newly-asserted defense to infringement under § 273. Section 273 creates "a prior-use defense for a defendant that 'commercially used' a claimed 'process' or 'machine, manufacture, or composition of matter used in a manufacturing or other commercial process' 'at least 1 year' before the earlier of the effective filing date of the claimed invention or a previous disclosure thereof." *BASF Corp. v. SNF Holding Co.*, 955 F.3d 958, 968 n.8 (Fed. Cir. 2020); 35 U.S.C. § 273(a). Unlike a non-infringement defense, this defense must be proven by the defendant "by clear and convincing evidence." 35 U.S.C. § 273(b). Here, Hospira's newly-asserted defense under § 273 is apparently based on Hospira and Pfizer's acquisition of the defense through third-party PLIVA's secret use of the claimed process. Compared to Hospira's prior-knowledge-and-use defense based on third-party PLIVA's actions (which hinge on Hospira's attempt to demonstrate that the claimed invention was accessible to the public), this new

defense raises new factual issues because it is a "Personal defense" and can be transferred only in certain circumstances. Specifically, § 273(e)(1) provides:

> **(A) In general.**—A defense under this section may be asserted only by the person who performed or directed the performance of the commercial use described in subsection (a), or by an entity that controls, is controlled by, or is under common control with such person.
>
> **(B) Transfer of right.**—Except for any transfer to the patent owner, the right to assert a defense under this section shall not be licensed or assigned or transferred to another person except as an ancillary and subordinate part of a good-faith assignment or transfer for other reasons of the entire enterprise or line of business to which the defense relates.
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> **(C) Restriction on sites.**—A defense under this section, when acquired by a person as part of an assignment or transfer described in subparagraph (B), may only be asserted for uses at sites where the subject matter that would otherwise infringe a claimed invention is in use before the later of the effective filing date of the claimed invention or the date of the assignment or transfer of such enterprise or line of business.

Because of these new factual issues, Hospira's previously-disclosed invalidity defenses cannot simply be repackaged into the newly-disclosed § 273 defense.

2. Amgen Has Been Deprived of the Opportunity to Take Discovery That It Would Have Taken to Respond to the § 273 Defense

The assertion of a § 273 infringement defense raises issues beyond the elements of the on-sale bar and prior-knowledge-and-use invalidity defenses. Having been deprived of the opportunity to take such discovery due to Hospira's non-disclosure of the defense, Amgen should not be prejudiced at the upcoming trial by Hospira's late injection of the issue into the case. *See, e.g., Orexigen*

Therapeutics, Inc. v. Actavis Lab'ys FL, Inc., No. 1:15-CV-451-RGA, 2017 WL 2221178, at *2 (D. Del. May 19, 2017) ("[i]t would be extremely prejudicial to allow Defendant to proceed at trial with arguments of failure of proof and non-infringement that were presented for the first time in the pre-trial order"); *Intellectual Ventures I LLC v. Symantec Corp.*, 2015 WL 294240, at *1 (D. Del. Jan. 21, 2015) ("it would be unfairly prejudicial to [plaintiffs] to allow [the defendant], at nearly the final moment before trial" to put plaintiffs in the position of responding to an additional defense). Moreover, having had the trial delayed once before due to Hospira's disclosure of new theories after the close of fact discovery, Amgen should not have its day with the jury postponed again because of Hospira's untimely disclosures.

For example, Amgen has not had the opportunity to take discovery on the following issues relevant to a § 273 infringement defense, and on which Hospira apparently intends for the jury to resolve disputed questions of fact.

a. Whether the right to assert a § 273 defense was transferred to Hospira from PLIVA through multiple acquisitions

35 U.S.C. § 273(e)(1)(A) limits the application of the defense where the defendant asserting the defense is not the person or entity who performed the prior use, or an entity that controls or is under common control with the entity performing the prior use. Whether the defense may be transferred depends on

factual issues such as whether there was a "transfer for other reasons of the entire enterprise or line of business to which the defense relates." 35 U.S.C. § 273(e)(1)(B).

Here, the alleged commercial use was performed by third-party PLIVA rather than either of Defendants Hospira or Pfizer. The series of transactions from third-party PLIVA to either Defendant is not straightforward, comprising at least four transactions over nine years.[4] Amgen has not taken discovery as to the facts and circumstances surrounding the transactions after the 2005 Development and Supply Agreement, as Amgen would have done had Hospira timely asserted a § 273 defense. Indeed, there was no reason for Amgen to seek discovery of the later transactions given Hospira's representation to the Court that Hospira was relying on the 2005 Agreement for its invalidity defense, and the later transactions are not relevant to that invalidity defense (as they would be to a § 273 defense): "those subsequent events are not relevant to the invalidity defense. The question is at the time of the sale, and the sale we're relying on is the 2005 agreement where

[4] The four transactions after the 2005 Development and Supply Agreement are: (1) a 2006 transaction involving Croatian company PLIVA and U.S. company Barr; (2) a 2008 transaction involving Barr and Israeli company Teva; (3) a 2009 transaction involving PLIVA (then part of Teva) and Defendant Hospira; and (4) a 2015 transaction involving Defendants Hospira and Pfizer.

Bar[r], were Bar[r] and Pliva, separate companies, and they were, and this was an arm's length transaction." Wu Decl. Ex. G at 37 ("Bar[r] ended up becoming part of the same company as Pliva, but those transactions aren't relevant here. What we're looking at is what happened in 2005. We're relying on that 2005 agreement for our defense.").

b. Whether Hospira or any of its predecessors abandoned the alleged prior-commercial use

35 U.S.C. § 273(e)(4) limits the application of the defense where a person has abandoned the alleged commercial use. Here, Amgen has not taken discovery as to the facts and circumstances surrounding abandonment, as Amgen would have done had Hospira timely asserted a § 273 defense.

c. Whether Hospira's current manufacturing site used the claimed invention before 2009

Where, as here, the defense is alleged to have been transferred among entities, 35 U.S.C. § 273(e)(1)(C) limits the application of the defense to "uses at sites where the subject matter that would otherwise infringe a claimed invention is in use before the later of the effective filing date of the claimed invention or the date of the assignment or transfer of such enterprise or line of business." In this case, Amgen has not taken discovery as to the facts and circumstances surrounding Hospira's current manufacturing site and when the claimed process invention was

first used there, as Amgen would have done had Hospira timely asserted a § 273 defense.

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Accordingly, Amgen respectfully requests that the Court strike Hospira's newly-asserted defense to infringement based on prior-commercial use under § 273, including from Hospira's pretrial exchanges. *See* Wu Decl. Ex. A; Wu Decl. Ex. B; Wu Decl. Ex. C; Wu Decl. Ex. D; Wu Decl. Ex. E.

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